

CORRECTED

In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

No. 20-660V

(not to be published)

PATRICIA KOAPKE, as parent and
natural guardian of W.K., a minor,

Petitioner,

v.

SECRETARY OF HEALTH AND
HUMAN SERVICES,

Respondent.

Chief Special Master Corcoran

Filed: July 7, 2022

Maximillian J. Muller, Muller Brazil, LLP, Dresher, PA, for Petitioner.

Sarah Christina Duncan, U.S. Department of Justice, Washington, DC, for Respondent.

DECISION¹

On May 29, 2019, Patricia Koapke filed a petition for compensation on behalf of her minor son, W.K., under the National Vaccine Injury Compensation Program. 42 U.S.C. §300aa-10, *et seq.*² (the “Vaccine Act”). Petitioner alleged a Table claim involving the injury of intussusception caused by the rotavirus vaccine. ECF No. 1, Petition (“Pet.”) at 1. The matter was assigned to the Special Processing Unit.

In September 2021, I dismissed the Table intussusception claim based on my finding that W.K.’s symptoms began outside the onset timeframe specified for such a claim. Ruling and Order, dated September 15, 2021 (ECF No. 18) (the “Show Cause Order”). I did not dismiss the case entirely, however, noting that a non-Table version of

¹ Because this unpublished decision contains a reasoned explanation for the action in this case, the undersigned intends to post it on the United States Court of Federal Claims' website, in accordance with the E-Government Act of 2002. 44 U.S.C. § 3501 note (2012)(Federal Management and Promotion of Electronic Government Services). In accordance with Vaccine Rule 18(b), petitioner has 14 days to identify and move to redact medical or other information, the disclosure of which would constitute an unwarranted invasion of privacy. If, upon review, the undersigned agrees that the identified material fits within this definition, the undersigned will redact such material from public access.

² National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3755. Hereinafter, for ease of citation, all section references to the Vaccine Act will be to the pertinent subparagraph of 42 U.S.C. § 300aa (2012).

the claim might be tenable – although Petitioner would need to substantiate how such a claim could succeed, given the existence of some relevant prior decisions suggesting a too-long onset was not medically acceptable. Show Cause Order at 6-7.

Both sides have now filed briefs on the topic. Petitioner's Brief, dated November 15, 2021 (ECF No. 22) ("Br."); Respondent's Opposition, dated December 6, 2021 (ECF No. 24) ("Opp."). Having reviewed the parties' submissions, I hereby dismiss the non-Table version of the claim, for the reasons set forth below.

ANALYSIS

A full summary of the facts is set forth in my prior decision dismissing the Table claim. See *generally* Show Cause Order at 2–3. In short, W.K. received the rotavirus vaccine on September 16, 2019. He was later diagnosed with intussusception,³ but did not become symptomatic until 26-28 days after receiving the vaccine, which is outside the 1-21 day timeframe set forth for a Table intussusception claim. Pet. at 1; Show Cause Order at 5. Accordingly, the Table claim could not tenably advance. *Id.* at 7. I noted, however, that Petitioner might be able to show a longer onset was medically acceptable, although she would need to provide some scientific or medical basis for allowing this to occur. *Id.* Therefore, I ordered her to show cause as to why this matter should be advanced as a non-Table claim, and to file an amended petition if she was asserting a causation-in-fact claim. *Id.*

Petitioner filed an amended petition on September 29, 2021, revising her claim to allege W.K.'s intussusception was caused in fact by the rotavirus vaccine. ECF No. 22, Petitioner's Response to Order ("Resp.") at 7. Petitioner's response to my Show Cause Order was subsequently filed on November 15, 2021, emphasizing that the case can move forward as a non-Table claim. Resp. at 7. Petitioner argued that the lack of on-point case law at least established that the contention about onset had never been explicitly rejected. See *Id.* at 6. Therefore, she should be given the opportunity to support this argument with an expert report and other persuasive evidence. *Id.* at 7. Petitioner did not, however, provide any evidence (whether a tentative report or item of medical/scientific literature) that in any way might support the conclusion that a post-vaccination intussusception onset of a week or more beyond the Table period might be medically acceptable.

³ The Table defines intussusception as "the invagination of a segment of intestine into the next segment of intestine, resulting in bowel obstruction, diminished arterial blood supply, and blockage of the venous blood flow" which typically causes sudden abdominal pain. 42 C.F.R. § 100.3(c)(4)(i).

Respondent reacted to Petitioner's filing on December 6, 2021, requesting the case be dismissed for reasons set forth in their Rule 4(c) Report. ECF No. 24, Respondent's Reply to Petitioner's Response ("Reply") at 5. Specifically, Respondent reiterated the contention that a longer onset of intussusception following the rotavirus vaccine was not medically acceptable. *Id.* This contention was supported by scientific evidence indicating symptoms onset would typically occur within *seven* days of vaccination, making the 21-day timeframe set forth in the table intentionally generous. *Id.* Respondent also noted that Petitioner had not been formally prevented from filing an expert report, and has had ample time to do so. *Id.* at 4. Moreover, Respondent emphasized that none of W.K.'s treating physicians believed the rotavirus vaccine caused his intussusception, and pointed to W.K.'s prolapsed appendix and the dusky purple nodular lesion in his bowel as alternative causes to his post-vaccination intussusception. *Id.* at 4–5. Thus, Respondent argued that Petitioner could not substantiate a causation-in-fact claim. *Id.* at 5.

I find that the *sui generis* nature of an intussusception injury claim weighs against allowing this petition to proceed. Intussusception is a unique injury in the Vaccine Program. Medical science supports an association with the rotavirus vaccine, albeit in a very short/acute timeframe. See National Vaccine Injury Compensation Program: Addition of Intussusception as Injury for Rotavirus Vaccines to the Vaccine Injury Table, 80 Fed. Reg. 35848 (June 23, 2015). But because intussusception can easily be treated quickly (via an invasive surgical procedure), the injury cannot satisfy the Act's severity requirement, since full recovery can occur well within six months of vaccination. 42 U.S.C. §300aa-11(c)(1)(D) (1998).

To get around this statutory contradiction, in 2000 the Vaccine Act was amended in response to the persuasive evidence linking the rotavirus vaccine and intussusception. See Children's Health Act, Pub. L. No. 106-310, § 1701, 114 Stat. 1101, 1151 (2000) (codified as amended at 42 U.S.C. §300aa-11(c)(1)(D)). The amendment added the Table claim, and an exception to the six-month severity requirement was also created for injuries requiring "surgical intervention." 42 U.S.C. §300aa-11(a)(XI)(A); 42 U.S.C. §300aa-11(c)(1)(D).

Although the Table intussusception claim allows any intussusception occurring within 21 days of vaccination to be actionable, this timeframe is *understood* to be overbroad. HHS emphasized in enacting the claim that the evidence *best* supported an increased risk of intussusception only one to seven days following vaccination (with peaks in the fourth and fifth days). 80 Fed. Reg. 35838. Thus, the 21-day timeframe set forth by the Table is more reflective of the Program's policy goals of generosity than what the science supports – and this in turn suggests that onset timeframes that exceed the Table

period are not likely to be medically reasonable, absent new research or discoveries showing that post-vaccination intussusception onset can occur in a longer timeframe than previously thought.

The above reasoning has been implicitly embraced in some causation-in-fact cases in which a timeframe onset well outside the Table period was alleged. See, e.g., *Carda v. Sec'y of Health & Hum. Servs.*, No. 14-191V, 2016 WL 3571539, at *2 (Fed. Cl. Spec. Mstr. Nov. 16, 2017). In *Carda*, (which I decided), the petitioners failed to prove that the rotavirus vaccine could cause transient intussusceptions that led to an acute episode requiring surgical intervention *eight weeks* after a second dose. While the facts of that case are not precisely on point, the result in *Carda* shows that an onset exceeding the Table period is not likely to be medically or scientifically reliable.

I have provided Petitioner herein the opportunity to identify *some* evidence suggesting that expert input would be worthwhile on this question of onset exceeding the Table timeframe (short of simply filing a report). But Petitioner has failed to offer any scientific/medical support for a longer onset. Nor has she pointed to any previous cases where the rotavirus vaccine was shown (in the context of a non-Table claim) to cause intussusception in a longer timeframe than what is established by the Table. Response at 8. The fact that no cases specifically reject the concept is not the same as a conclusion that evidence *supports* it.

Petitioner nevertheless asks for the opportunity to identify an expert who “might” be able to support the claim with an opinion. Response at 8. But special masters are tasked with determining what evidence is relevant or required to resolve a given case. Vaccine Rules 3(b)(1), 7(a), 8(a). They may therefore deny requests to offer evidence when the effort is likely to be futile. And here, Petitioner has not demonstrated any more than a hope that a longer onset could be defended – despite a fair opportunity, she has not offered any evidence at all that would suggest a 26 to 28 day post-vaccination onset could be medically acceptable for an injury otherwise understood to occur close-in-time to vaccination. Therefore, given the unique nature of an intussusception injury, and the science supporting only a fraction of the Table’s onset timeframe, I do not find that expert input on this matter is likely to be fruitful or result in an efficient and expeditious determination.

There is no doubt that a petitioner’s inability to meet all the Table elements of a given claim does not always mean the entire petition should be dismissed. Rather, for some kinds of injuries, fairness dictates that the petitioner be allowed the opportunity to prove a causation-in-fact version of their claim. For example, a flu-GBS Table claim is not viable, even if onset occurs in the defined timeframe, when the injury turns out to be CIDP

– yet such a claim provides reasonable grounds for a causation-in-fact claim. See, e.g., *Nieves v. Sec’y of Health & Hum. Servs.*, No. 18-1602V, 2021 WL 841488 (Fed. Cl. Spec. Mstr. Jan. 11, 2021) (dismissing Table flu-GBS claim where CIDP was established injury, but allowing non-Table claim to proceed based on same set of facts). And I have tried cases in which a claimant could not meet a Table claim’s onset timeframe, but it appeared that some science existed to support the contention that a longer timeframe might be medically acceptable. See, e.g., *Greene v. Sec’y of Health & Hum. Servs.*, No. 11-631V, 2019 WL 4072110 (Fed. Cl. Spec. Mstr. Aug. 2, 2019) (dismissing non-Table claim of brachial neuritis after Tdap vaccine; petitioner offered reasonable evidence that longer onset was medically acceptable, even though he was ultimately unsuccessful), *mot. for review den’d*, 146 Fed. Cl. 655, 669 (2020), *aff’d*, 841 F. App’x. 195, 205 (Fed. Cir. 2020). But the idiosyncratic nature of intussusception as a vaccine injury calls for a different outcome entirely. An onset of 26 to 28 days post-vaccination is simply not likely to be medically acceptable, given what is known about intussusception.

For these reasons, **Petitioner’s causation-in-fact claim for compensation is DISMISSED**. In the absence of a motion for review filed pursuant to RCFC Appendix B, the Clerk of the Court SHALL ENTER JUDGMENT in accordance with the terms of this Decision.⁴

IT IS SO ORDERED.

s/Brian H. Corcoran
Brian H. Corcoran
Chief Special Master

⁴ Pursuant to Vaccine Rule 11(a), the parties may expedite entry of judgment if (jointly or separately) they file notices renouncing their right to seek review.